EXHIBIT A

Household Products Database

National Institutes of Health
National Library of Medicine
Specialized Information Services

Chemical Information

Chemical Name: **Octoxynol 9**

CAS Registry Number: 009002-93-1

Synonyms: Octoxynol; PEG-# octyl phenyl ether where # = 9,11,12,25, or 33; Polyethylene glycol (#) octyl phenyl ether where # = 11,25,33,450,600 or 2000; Octoxynol-9, -11, -12, -25, -33, or -40; PEG-40 Octyl phenyl ether; Triton X-# where # = 45,100 or 102

Information from other National Library of Medicine databases

Health Studies: ***No information available in HSDB at this time***

Toxicity Information: Search TOXNET

Chemical Information: Search ChemIDplus

Biomedical References: Search PubMed

Products that contain this ingredient

Brand	Category	Form	Percent
Garage Magic	Home maintenance	aerosol	<2.9
St. Ives Hair Repair Thickening Shampoo Volumizing Treatment For Fine Hair	Personal care/use	liquid	
Grecian Formula 16, Liquid with Conditioner	Personal care/use	liquid	
Jumping Curls	Personal care/use	pump spray	
Nair Hair Remover Kit, Cold Wax Strips Pretreatment Towelette	Personal care/use	wax	

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National Institutes of Health, Department of Health & Human Services
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Last updated: April 23, 2007

EXHIBIT B

Vaginitis

From Wikipedia, the free encyclopedia

Vaginitis is an inflammation of the vaginal mucosa and often associated with an irritation or infection of the vulva leading to **vulvovaginitis**. It is a common problem.

Vaginitis *Classification & external resources*	
ICD-10	N76.0 (http://www.who.int/classifications/apps/icd/icd10online/?gn70.htm+n760)-N76.1 (http://www.who.int/classifications/apps/icd/icd10online/?gn70.htm+n761)
ICD-9	616.1 (http://www.icd9data.com/getICD9Code.ashx?icd9=616.1)
DiseasesDB	14017 (http://www.diseasesdatabase.com/ddb14017.htm)
eMedicine	med/3369 (http://www.emedicine.com/med/topic3369.htm) med/2358 (http://www.emedicine.com/med/topic2358.htm) emerg/631 (http://www.emedicine.com/emerg/topic631.htm) emerg/639 (http://www.emedicine.com/emerg/topic639.htm)

Contents

Significance

Vaginitis may be asymptomatic, but usually leads to significant vaginal itching and irritation so that the patient self-medicates or seeks professional help. If it is caused by an infectious organism such as chlamydia, the infection progress throughout the uterus into the fallopian tubes and ovaries and could lead to infertility. An infection via human papillomavirus (HPV) can eventually increase the risk of cervical carcinoma.

Symptoms

A woman with this condition may have itching or burning and may notice a discharge. In general, these are symptoms of vaginitis:

- irritation and/or itching of the genital area
- inflammation (irritation, redness, and swelling caused by the presence of extra immune cells) of the labia majora, labia minora, or perineal area
- vaginal discharge

- foul vaginal odor
- discomfort or burning when urinating
- pain/irritation with sexual intercourse

Causes

Vulvovaginitis can affect women of all ages and is very common. Specific forms of vaginitis are:

Infection

Infectious vaginitis accounts for 90% of all cases in reproductive age women and is represented by the triad:

- Candidiasis: vaginitis caused by *Candida albicans* (a yeast),
- Trichomoniasis: vaginitis caused by *Trichomonas vaginalis* (a protozoan),
- Bacterial vaginosis: vaginitis caused by *Gardnerella* (a bacterium).

Other less common infections are caused by *gonorrhea*, *chlamydia*, *mycoplasma*, *herpes*, *campylobacter* and some *parasites*.[1]

Hormonal

Hormonal vaginitis includes atrophic vaginitis usually found in postmenopausal or postpartum women. Sometimes it can occur in young girls before puberty. In these situations the estrogen support of the vagina is poor.

Irritation/allergy

Irritant vaginitis can be caused by allergies to condoms, spermicides, soaps, perfumes, douches, lubricants and semen. It can also be caused by hot tubs, abrasion, tissue, tampons or topical medications.

Foreign body

Foreign Body Vaginitis: Foreign bodies (most commonly retained tampons or condoms) cause extremely malodorous vaginal discharges. Treatment consists of removal, for which ring forceps may be useful. Further treatment is generally not necessary.

Role of STD's

Sexually Transmitted Diseases (STDs) can be a cause of vaginal discharge. Chlamydia and gonorrhea testing should be done whenever a sexually active adolescent complains of vaginal discharge even when the cervix appears normal.

Discharge

The color of the discharge may be predictive of the causative agent. (ICD-10 codes for causative agents listed below.)

- (B37. (http://www.who.int/classifications/apps/icd/icd10online/?gb35.htm+b37)) Candida Vaginitis *Candidiasis* usually causes a watery, white, cottage cheese like vaginal discharge. The discharge is irritating to the vagina and the surrounding skin.

- (N95.2 (http://www.who.int/classifications/apps/icd/icd10online/?gn80.htm+n952)) Atrophic vaginitis (or "Senile Vaginitis") usually causes scant vaginal discharge with no odour, dry vagina and painful intercourse. These symptoms are usually due to decreased hormones usually occurring during and after menopause.

- (B96.3 (http://www.who.int/classifications/apps/icd/icd10online/?gb95.htm+b963)) Bacterial Vaginitis *Gardnerella* usually causes a discharge with a fish-like odour. It is associated with itching and irritation, but not pain during intercourse.

- (A59.0 (http://www.who.int/classifications/apps/icd/icd10online/?ga50.htm+a590)) Trichonomas Vaginitis *Trichomonas vaginalis* can cause a profuse discharge with a fish-like odour, pain upon urination, painful intercourse, and inflammation of the external genitals.

- (A60.0 (http://www.who.int/classifications/apps/icd/icd10online/?ga50.htm+a600)) Herpes usually occurs as water blisters on the genital region, about one week after infection. There is tenderness, swollen glands, and fever. The water blisters are extremely painful and heal in about three weeks. However, herpes is usually an external infection and does not fall under the category of vaginitis.

Women who have diabetes frequently develop vaginitis, often Candida *Candida albicans* more often than women who do not.

Diagnosis

It may be useful to measure the PH value as with infections vaginal pH increases. Diagnosis is made with microscopy and culture of the discharge after a careful history and physical examination have been completed.

Complications

- persistent discomfort
- superficial skin infection (from scratching)
- complications of the causative condition (such as gonorrhea and candida infection)

Treatment

The cause of the infection determines the appropriate treatment. It may include oral or topical antibiotics and/or antifungal creams, antibacterial creams, or similar medications. A cream containing cortisone may also be used to relieve some of the irritation. If an allergic reaction is involved, an antihistamine may also be prescribed. For women who have irritation and inflammation caused by low levels of estrogen (postmenopausal), a topical estrogen cream might be prescribed.

References

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- Jaquiery A, Stylianopoulos A, Hogg G, et al: Clinical features, aetiology, and microbiology of the genital tract. Arch Dis Child 81:64, 1999. (http://www.health.am/gyneco/more/vaginitis/Vulvovaginitis:)
- Brook I: Microbiology and management of polymicrobial female genital tract infections in adolescents. J Pediatr Adolesc Gynecol 2002;15(4):217. PMID 12459228 (http://www.ncbi.nlm.nih.gov/pubmed/12459228).
- Joesoef MR, Schmid GP, Hillier SL. Bacterial vaginosis: review of treatment options and potential clinical indications for therapy. 1999;28(suppl 1):S57-S65. (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed&cmd=Search&defaultField=Title+Word&term=CID%5Bjour%5D+AND+28%5Bvolume%5D+AND+S57%5Bpage%5D+AND+1999%5Bpdat%5D+AND+Joesoef+MR%5Bauth%5DCID)
- Reed B, Slatery M, French T. Diet and vaginitis. Fam Pract 1989;29:509-15. (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed&cmd=Search&defaultField=Title+Word&term=J+Fam+Pract%5Bjour%5D+AND+29%5Bvolume%5D+AND+509%5Bpage%5D+AND+1989%5Bpdat%5D+AND+Reed+B%5Bauth%5DJ)
- Rodgers CA, Beardall AJ: Recurrent vulvovaginal candidiasis: Why does it occur? Int J STD AIDS 10:435; quiz 440, 1999. (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed&cmd=Search&defaultField=Title+Word&term=Int+J+STD+AIDS%5Bjour%5D+AND+10%5Bvolume%5D+AND+435;+quiz+440%5Bpage%5D+AND+1999%5Bpdat%5D)

1. ^ Template:Cite literature

See also

- Vulvovaginal health
- Atrophic vaginitis

External links

- *Vaginitis (http://www.emedicine.com/emerg/topic631.htm)* at eMedicine
- DDB *14017 (http://www.diseasesdatabase.com/ddb14017.htm)*
- Vulvovaginitis (http://www.3-rx.com/vaginitis/default.php) - Overview, Causes, & Risk Factors | Symptoms & Signs | Diagnosis & Tests | Prevention & Expectations | Treatment & Monitoring

Retrieved from "http://en.wikipedia.org/wiki/Vaginitis"
Categories: General practice | Gynecology | Inflammations

EXHIBIT C

Exhibit C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Syed Rizvi	)	
	)	
Serial No.: 10/780,661	)	Examiner: Ghali, Isis A.
	)	
Filed: February 19, 2004	)	
	)	Art Unit: 1615
For: **Feminine Wipe for Symptomatic Treatment of Vaginitis**	)	

DECLARATION UNDER 37 C.F.R. § 132

I, Dr. Syed Rizvi, am the sole inventor in U.S. Patent Application No. 10/780,661 (the "Rizvi Application"). This declaration is being submitted in response to a non-final office action rejecting claims 1-10 of the Rizvi Application.

I understand that the claims were rejected under 35 U.S.C. § 103(a), as potentially being obvious by several prior art publications consisting of (1) the article "Compendium of Pharmaceutical Excipients for Vaginal Formulations" by Garg et al. ("Garg et al."), (2) U.S. Patent Application Publication 2002/0142690 ("US '690"), and the article "Natural Deodorant" by Carrubba, Inc. ("Carrubba Inc.").

I have reviewed the Office Action issued by the U.S. Patent & Trademark Office on September 27, 2007. In support of all current rejections, the Examiner relies upon the Garg et al. reference. The Examiner cites and relies upon the following composition from Garg et al. on page 3 of the Office Action. (Garg et al. p.17).

Massengill	Towel	SmithKline Beecham	Lactic acid, water, sodium lactate, potassium sorbate, O-9, EDTA, cetylpyridinium chloride, fragrance	Cleanse external vaginal area

There are certain embodiments of my invention, which are capable of controlling odor without the use of a fragrance (which would otherwise only mask an odor). The

Garg et al. formulation shown above expressly recites the use of a "fragrance." My invention - in certain embodiments - is substantially different in that regard. For example, it is my understanding that the scope of Claims 4 and 7 exclude the use of a fragrance. As such, the Garg et al. formulation relied upon is materially different than the composition recited in, for example, Claims 4 and 7. The following will briefly describe the results of previous testing of the claimed devices that I supervised and controlled.

Prior to filing the Rizvi Application, I engaged an independent laboratory to test the odor absorbing properties of the devices and methods of the present invention. I hired Odor Science & Engineering, Inc. (OS&E). The product tested was and still is known as the "Mystique Feminine Wipes," which consisted of an absorbent fabric impregnated with a liquid consisting essentially of 5% saccharomyces ferment, 0.50% oxytoxynol-9, 0.20% potassium sorbate, 0.20% cetylpyridinium chloride, 0.10% disodium EDTA, and 0.05% lactic acid. The product was not provided with and did not employ any "fragrance."

The test results demonstrated that the present invention is capable of reducing "headspace feminine odor" by 74%. This is a significant reduction in "headspace feminine odor," particularly considering that the device / liquid combination did not include a fragrance. The relevant portions of the protocol and results of OS&E's testing is described in further detail in **Exhibit 1** to this Declaration.

The foregoing facts and supporting **Exhibit 1** establish that certain embodiments of my invention, such as those of Claims 4 and 7, are capable of controlling odor without using a fragrance. This is a material distinction from the formulation cited in Garg et al.

I, Syed Rizvi, hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Syed Rizvi

Dr. Syed Rizvi

3-18-08

Date

Exhibit 1

Test Protocol

OS&E was sent samples of both the Mystique Feminine Wipes material and the Mystique Feminine Wipes solution (pH 6.0). The dry wipe fabric used for this test was:

Wipe: 2.167 x 3.5
Towel: 4" x 5.25"

The dry wipe sample was placed on an odor-free plastic dish. Six (6) mls of the Mystique Feminine Wipes solution were added to the cloth sample as the wetting agent.

OS&E prepared an odor surrogate solution appropriate for this product's application which was comprised of the following compounds:

500 ml distilled water
0.1 ml strong ammonia solution
0.1 ml trimethyl amine
0.1 ml cadaverine

A 1ml volume of the odor solution was applied to cover the entire surface area of the Mystique Feminine Wipes wetted sample.

Immediately following the application of the wipe wetting agent and the odor surrogate solution, the wipe sample was placed into a 25 liter Tedlar gas sampling bag and sealed. The bag was then filled with 20 liters of carbon-filtered, odor-free air and maintained at room temperature for a 24-hour period.

A 1ml volume of the odor surrogate solution was injected into 25 liter Tedlar bag containing 20 liters of carbon-filtered odor-free air to evaluate the odor of the surrogate odor solution alone.

After 24 hours, the headspace air in each bag was transferred into 12 liter preconditioned Tedlar bags and submitted for sensory evaluation.

The samples were analyzed by dynamic dilution olfactometry using a trained and screened odor panel of 8 members. The odor panelists were chosen from OS&E's pool of panelists from the Greater Hartford area who actively participate in ongoing olfactory research and represent an average to above average sensitivity when compared to a large population. The samples were quantified in terms of dilution-to-threshold (D/T) ratio and odor intensity in accordance with ASTM Methods E-679-91 and E-544-99, respectively. These test methods are further described in Attachment A. The odor panelists were also asked to describe the odor character and rate the hedonic tone (degree of pleasantness or unpleasantness) of each sample at a fixed dilution level of 5.

The results of the odor panel tests are presented in the attached Table 1.

Results

The odor level of the odor surrogate solution alone was 23 D/T. The surrogate odor was described by the panelists' as a mixture of predominately the "fishy/urine" (trimethyl amine) and the "rotten/cadaverous" (cadaverine) components. At a fixed dilution level of 5 the average of the 8 odor panelists' intensity rating was 3.75 as referenced on the 8-point n-butanol intensity scale. The average hedonic tone rating of the panelists at this same dilution level was –5 which is between moderately to very unpleasant.

When this same odor surrogate was added to the Mystique Feminine Wipes sample, the headspace odor concentration was reduced to 6 D/T (74% reduction). The faint odor that was perceived in this sample was described as "sweet/fruity/alcohol/medicinal" odor character (that of the Mystique solution, rather than the surrogate odor compounds).

Table 1. Odor Panel Results – 8/9/01
Humana USA Inc. – Mystique Feminine Wipes
OS&B Project No. 1161-M-00

Sample			24-hour headspace odor conc. (D/T)[a]	Odor panelists assessment at fixed sample dilution level of 5		
Test Media	Wetting Agent added	Odor Surrogate Solution added		Intensity[b]	Hedonic Tone[c]	Character[d]
no wipe	none	1 ml	23	3.75	-5 (moderate-very unpleasant)	fishy, sour, rotten potatoes, rotten fish, rendering, pig fat, urine, cadaverous, NH_3, fecal
wipe[e]	6 mls Mystique Feminine Wipes Solution (pH 6.0)	1 ml	6	1.0	+1 (neutral – slightly pleasant)	sweet, alcohol, medicinal, fruity, cough medicine, soap, laundry detergent, raspberries

a) odor concentration; D/T = dilutions-to-threshold as measured by ASTM Method E-679-91
b) Average of odor panelists intensity rating based on the n-butanol intensity reference scale (0-8) ASTM Method E-544-99
c) Average of odor panelists hedonic tone rating, measuring the degree of pleasantness or unpleasantness –8 (most unpleasant) through 0 (neutral) to +8 (most pleasant)
d) odor descriptors used by the odor panelists
e) wipe material = Mystique Feminine Wipes fabric: Film: WPL 2.167" x 3.5" Towel: WN 4" x 5.25"

Odor Science & Engineering, Inc. 1350 Blue Hills Avenue Bloomfield, CT 06002
phone: (860) 243-9380 fax: (860) 243-9431 www.odorscience.com

ATTACHMENT A

Measurement of Odor Concentration by Dynamic Dilution Olfactometry

Odor concentration or detectability is defined as the dilution which is required to reduce the odor intensity to the level at which only a specified percent of human population, typically 50%, will detect the odor. This point represents detection threshold. Odor concentration is determined by means of OS&E's dynamic dilution forced choice olfactometer. Known dilutions of the odor sample are prepared by mixing a stream of odor-free air with a stream of the odor sample.

The odor-free air is generated in-situ by passing the air from a compressor pump through a bed of activated charcoal and a potassium permanganate medium for purification. A portion of the odor free air is diverted through a valve and a rotameter where it is split into two streams for direct presentation to a panelist who compares them with the diluted odor sample.

Another portion of the odor-free air passes through a precision flow meter and subsequently enters a venturi ejector. The flow of the odor-free air through the venturi creates a negative pressure which is used to aspirate the odor sample from the sample bag into the venturi for mixing.

A panelist is presented with three identical nose cups, two of which provide a stream of odor-free air and the third one a known dilution of the odor sample. Unaware of which is which, the panelist is asked to identify the cup which is different from the other two, i.e., which contains the odor. The flow rate at all three nose cups is maintained at 3 liters per minute. The nose cups are made of glass. They are funnel shaped with a diameter of 6 cm to allow for full insertion of the panelist's nose.

The analysis starts at high odor dilutions. Odor concentration in each subsequent evaluation is increased by a factor of 2. Initially a panelist is unlikely to correctly identify the nose cup which contains an odor. As the concentration increases, the likelihood of error is reduced and at one point the response at every subsequently higher concentration becomes consistently correct. The lowest odor concentration at which this consistency is first noticed, represents the detection odor threshold for that panelist. As the odor concentration is increased further in the subsequent steps, the panelist becomes aware of the odor character, i.e. becomes able to differentiate the analyzed odor from other odors. The lowest odor concentration at which odor differentiation first becomes possible, represent the recognition odor threshold for the panelist. Essentially all of OS&E's work is done with recognition odor threshold.

The panelists typically arrive at threshold values at different concentrations. To interpret the data statistically, the geometric average of the individual panelists' threshold is used.

The olfactometer and the odor presentation procedure meet the recommendations of ASTM Standard Practice for Determination of Odor and Taste Thresholds by a Forced-Choice Ascending Concentration Series of Limits (ASTM E679-91).

Odor Intensity

Odor intensity is determined using reference sample method with n-butanol as the referenc compound. The now widely used n-butanol odor intensity scale is based on n-butanol vapor a odorant at eight concentrations. The concentration increases by a factor of two at each intensit step, starting with approximately 15 ppm at step 1 and ending at approximately 2,000 ppm a step 8.

Odors of widely different types can be compared on that scale just like the intensities of th lights of different colors can be compared to the intensity of standard, e.g. white light. Odo character and hedonic tone are ignored in that comparison. The OS&E odor scientists use the n butanol scale in their work daily, both in the field and in the laboratory. In the process they hav memorized the scale which makes its use quite convenient in the field.

Odor intensities are also routinely measured as part of the dynamic dilution olfactometr measurements. The n-butanol vapor samples are presented to the panelists in closed jar containing the standard solutions of n-butanol in distilled water. The vapor pressure above th butanol solutions corresponds to the steps on the n-butanol scale. To observe the odor intensity, a panelist opens the jar and sniffs the air above the liquid. The panelist then closes the jar so tha the equilibrium vapor pressure of butanol can be re-established before the next panelist uses th jar. The odor in the jar is compared with unknown odor present at the olfactometer sniff port.

The relationship between odor concentration and intensity can be expressed as a psychophysical power function also known as Steven's law. The function is of the form:

$$I = aC^b$$

where:

I = odor intensity on the butanol scale
C = the odor level in dilution-to-threshold ratio (D/T)
a,b – constants specific for each odor

The major significance of the psychophysical function in odor control work is that it determines the rate at which odor intensity decreases as the odor concentration is reduced (either by atmospheric dispersion or by an odor control device). The function can therefore by used in predicting the reduction in odor concentration which is required to bring the odor intensity down to a desired level, judged not objectionable.

Odor Character Description

Odor character refers to our ability to recognize the similarity of odors. It allows us to distinguish odors of different substances on the basis of experience using general descriptors such as "sweet", "pungent", "acrid", etc. or specific references to its source such as "orange", "skunk", "paint", "sludge", etc. In the course of the dynamic dilution olfactometry measurements, the odor panelists are asked to describe the character of the odors they detect. They are told to use their own words and are given a standardized list of 146 different descriptors

adapted from Harper's Scale of odor-quality descriptors to use as a guide. The most predominant odor characters are reported for each sample.

Hedonic Tone

The hedonic tone refers to the degree of pleasantness or unpleasantness of the sensation. In the course of the dynamic dilution olfactometry measurements, the odor panelists are asked to rate their perception of this quality using a 17-point scale ranging from –8 (extremely unpleasant) to +8 (extremely pleasant). A value of 0 represents a neutral odor. The average hedonic tone rating of the panelists at a specified dilution level is reported for each sample.